



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Application No. : 10/084,676 Confirmation No. : 2539
First Named Inventor : Iris ZIEGLER
Filed : February 28, 2002
TC/A.U. : 1618
Examiner : Blessing Fubara

Docket No. : 029310.50932
Customer No. : 23911

Title : Oral Pharmaceutical Forms of Administration with a
Delayed Action

**SUBMISSION ACCOMPANYING REQUEST
FOR CONTINUED EXAMINATION**

Mail Stop RCE
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

Attention is directed to the accompanying Declaration of Dr. Iris Ziegler which reports in detail the results of two sets of tests demonstrating that the claimed product of the invention produced by the claimed process of the invention is different from a product produced according to the teachings of the cited Mauskop patent, US 5,914,129. The first set of tests shows that the claimed, *in situ* formed compound of Diclofenac-sodium and Tramadol-hydrochloride produced by the claimed process has a distinctly different release profile than a corresponding composition containing a mixture of Diclofenac-sodium and Tramadol-hydrochloride produced in accordance with the teachings of Mauskop. The second set of Differential Scanning Calorimetry (DSC) tests confirms that the claimed product of the invention produced by the claimed process of the invention contains a physical/chemical entity (i.e., an *in situ* formed compound) which is not present in the corresponding composition containing containing a mixture of Diclofenac-sodium and Tramadol-hydrochloride produced in accordance with the teachings of Mauskop. The test results thus establish that Mauskop does not anticipate the claimed product.

Moreover, the reported test results for the claimed invention are unexpected and surprising, since the results could not have been expected or predicted based on the disclosure of Mauskop or any other prior art of record. In particular repeating the moistening and mixing steps as claimed in claim 38 would not have been obvious to a person of ordinary skill because he/she would not have been aware of any purpose to be served by such repetition, and it is improper to assume that a skilled worker would find it obvious to carry out steps which serve no purpose. A person of ordinary skill in the art would have had no way of knowing that the repetition of such steps would contribute to the production of an *in situ* formed compound with the unexpected and surprising properties documented in the Ziegler Declaration. Therefore, Applicants respectfully submit that their claimed invention is non-obvious and patentable over Mauskop.

For the record, Applicants note that the criticism in the Office Action mailed November 17, 2005 of the previous Declaration of Dr. Ziegler submitted October 13, 2005 is erroneous. In paragraph 2 on page 3 of the Office Action it is alleged that Test 1 of the Ziegler Declaration was directed to release of individual Diclofenac and Tramadol compositions and not to a mixture of Diclofenac and Tramadol. This allegation is not correct. Test 1 of the previous Ziegler Declaration, like the tests of the accompanying Declaration, is directed to tests of compositions containing a mixture of Diclofenac-sodium and Tramadol-hydrochloride. To the extent that the assertion of unpatentability in the Office Action mailed November 17, 2005 was based upon this false interpretation of the Declaration, it is clearly erroneous and should be withdrawn.

In view of the foregoing discussion and the accompanying Declaration evidence, the application is respectfully submitted to be in condition for allowance, and prompt, favorable action thereon is earnestly solicited.

If there are any questions regarding this response or the application in general, a telephone call to the undersigned at (202) 624-2845 would be


Application No. 10/084,676
Submission Accompanying Request
for Continued Examination
December 15, 2006

appreciated since this should expedite the prosecution of the application for all concerned.

If necessary to effect a timely response, this paper should be considered as a petition for an Extension of Time sufficient to effect a timely response, and please charge any deficiency in fees or credit any overpayments to Deposit Account No. 05-1323 (Docket # 029310.50932).

Respectfully submitted,

December 15, 2006



J. D. Evans
Registration No. 26,269

CROWELL & MORING LLP
Intellectual Property Group
P.O. Box 14300
Washington, DC 20044-4300
Telephone No.: (202) 624-2500
Facsimile No.: (202) 628-8844
JDE:moi
doc. no. 2925689